IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: COLOPLAST CORP.
PELVIC SUPPORT SYSTEMS PRODUCTS LIABILITY LITIGATION — MDL NO. 2387

THIS DOCUMENT RELATES TO:

Janie Smith v. Coloplast Corp. — *Civil Action No. 2:13-cv-15065*

MEMORANDUM OPINION & ORDER

Pending before the court is Coloplast Corp.'s Motion for Summary Judgment [ECF No. 20]. The plaintiff has not responded, and the time for responding has expired. Thus, the Motion is ripe for adjudication. For the reasons set forth below, the Motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 25,000 cases currently pending, approximately 150 of which are in the Coloplast Corp. ("Coloplast") MDL, MDL 2387.

On September 8, 2010, Dr. Beverly Fuller surgically implanted Ms. Smith with the Suspend-Tutoplast Processed Fascia Lata ("Fascia Lata"), a device distributed by Coloplast to treat SUI and to reconstruct the pelvic floor. Short Form Compl. ¶¶ 9–12 [ECF No. 1]. Ms. Smith's surgery took place at Rogue Valley Medical Center in

Medford, Oregon. *Id.* at ¶ 11. Ms. Smith does indicate that she was ever implanted with any other transvaginal mesh product.

On March 19, 2013, Dr. Timothy Hutchings performed surgery on Ms. Smith to treat her vaginal pain. Def.'s Mot. for Summ. J. Ex. 7, at 2 [ECF No. 20-7] ("Hutchings Operative Report"). The surgery included "[r]emoval of vaginal mesh/foreign body/scar tissue." *Id.* A pathology report from the surgery specifically identified the material removed from Ms. Smith as "[v]aginal **synthetic** mesh." Def.'s Mot. for Summ. J. Ex. 8, at 2 [ECF No. 20-8] ("Pathology Report") (emphasis added).

Ms. Smith claims that as a result of the implantation of the Fascia Lata, she has experienced multiple complications. She adopts the following counts as alleged in the First Amended Master Long Form Complaint and Jury Demand ("Master Complaint"): I – negligence, II – strict liability design defect, III – strict liability manufacturing defect, IV – strict liability failure to warn, V – strict liability defective product, VI – breach of express warranty, VII – breach of implied warranty, VIII – fraudulent concealment, IX – constructive fraud, X – discovery rule and tolling, XI – negligent misrepresentation, XII – negligent infliction of emotional distress, XIII – violation of consumer protection laws, XIV – gross negligence, XV – unjust enrichment, and XVII – punitive damages. *Id.* at ¶ 13.

According to the Master Complaint, Coloplast "designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products," one of which was an allograft, the Fascia Lata. First Am. Master Compl. ¶¶ 22–23 [ECF No. 49], *In re Coloplast Corp., Pelvic Support Sys. Prods.*

Liab. Litig., No. 2:12-md-02387. Coloplast admits in its Joint Master Long Form Answer and Affirmative Defenses to Plaintiffs' First Amended Master Long Form Complaint and Jury Demand ("Master Answer") that it "generally packaged, labeled, marketed, sold[,] and distributed" such pelvic mesh devices. Master Answer ¶ 22 [ECF No. 62], *In re Coloplast Corp., Pelvic Support Sys. Prods. Liab. Litig.*, No. 2:12-md-02387. The Fascia Lata device consists of human collagen from donated human tissue. *See* Def.'s Mot. for Summ. J. Ex. 9, at 2 [ECF No. 20-2] ("Package Insert"). The Fascia Lata is preserved such that it "retains the unidirectional and mechanical properties of native Fascia Lata, while providing the basic formative structure to support replacement by new endogenous tissue." *Id.*

II. Legal Standards

a. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict" in his

or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

b. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation." *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of

each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as Ms. Smith did in this case, I consult the choice-of-law rules of the state in which the implantation surgery took place. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). Ms. Smith received her implantation surgery in Oregon. Short Form Compl. ¶¶ 11. Thus, the choice-of-law principles of Oregon guide this court's choice-of-law analysis.

In tort actions, Oregon uses "the 'most significant relationship' test" in its choice-of-law analysis. *Portland Trailer & Equip., Inc. v. A-1 Freeman Moving & Storage, Inc.*, 49 P.3d 803, 809 (Or. Ct. App. 2002) (citing *Erwin v. Thomas*, 506 P.2d 494, 494 (Or. 1973)). To determine which jurisdiction has the "most significant relationship" to the cause of action, courts should consider "(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicil[e], residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any between the parties is

centered." *Id.* at 810 (alteration in original) (paragraph breaks omitted) (quoting Restatement (Second) of Conflicts § 145(2) (1971)).

Here, Ms. Smith is an Oregon resident. Short Form Compl. ¶ 4. In addition, Ms. Smith's implantation surgery and alleged injuries occurred in Oregon. *Id.* at ¶¶ 11. Therefore, I find that Oregon has the most significant relationship with the case, and I apply Oregon substantive law to Ms. Smith's tort claims.[1]

III. Discussion

Coloplast argues that it is entitled to summary judgment on all of Ms. Smith's claims. First, Coloplast argues that, because the Fascia Lata is human tissue, it is not a "product" subject to products liability concepts. Therefore, all of Ms. Smith's claims sounding in products liability or breach of warranty must fail as a matter of law. Second, Coloplast argues that Ms. Smith's medical records show that the cause of her alleged injuries was the synthetic mesh product that she had removed on March 19, 2013—not the Fascia Lata distributed by Coloplast. Therefore, Ms. Smith cannot establish a causal link between her alleged injuries and Coloplast's conduct (i.e. distributing the Fascia Lata) and her negligence claims must fail as a matter of law.

a. Strict Liability and Breach of Warranty (Counts II–VII)

Coloplast argues that it is immune from the plaintiff's strict liability and warranty claims alleged in Counts II-VII because the Fascia Lata is human tissue, not a "product" subject to products liability concepts. Oregon's "blood shield" statute

[1] Coloplast agrees that Oregon substantive law applies to Ms. Smith's claims. Def.'s Mot. for Summ. J. at 5.

excludes the distribution of human body parts from the definition of a sales transaction subject to warranties:

> (1) The procuring, processing, furnishing, **distributing**, administering or using **of any part of a human body** for the purpose of injecting, transfusing or transplanting that part into a human body **is not a sales transaction covered by an implied warranty** under the Uniform Commercial Code or otherwise.
>
> (2) As used in this section, **"part" means** organs or parts of organs, **tissues**, eyes or parts of eyes, bones, arteries, blood, other fluids and any other portions of a human body.

Or. Rev. Stat. § 97.985 (emphases added). In interpreting this statute, the Court of Appeals of Oregon made clear that, although the statute does not expressly mention strict liability, "[t]he legislative history makes plain that that the legislature intended to preclude liability without fault, whatever its nature." *Royer v. Miles Lab., Inc.*, 811 P.2d 644, 647 (Or. Ct. App. 1991).[2] The Court of Appeals also noted, "The main focus of [the statute] is on declaring that the transactions do not constitute sales. Because strict liability cannot arise without there having been a sale, defendants could not be strictly liable." *Id.*

Similarly, the plaintiff's claim for express warranty must also fail. As the Fifth Circuit has explained:

> It is axiomatic, of course, that breach of express warranty is not available as a cause of action without a sale, because the essence of warranty is a consensual agreement— express or implied— arising from contract. Without a sale

[2] The term "products liability" is used in reference to both strict liability and breach of warranty claims. See 63 Am. Jur. 2d *Products Liability* § 625 (2010) ("An action for products liability may be brought under several theories, including . . . strict liability, and warranty.").

> under contract, there is no consensual nexus between the parties and thus no warranties may attach.

Heirs of Fruge v. Blood Servs., 506 F.2d 841, 846 (5th Cir. 1975) (citations omitted) (interpreting a statute defining tissue as a medical service and expressly exempting contracts for the sale of human tissue from breach of warranty claims); *see also Condos v. Musculoskeletal Transplant Found.*, 208 F. Supp. 2d 1226, 1227 & n.1 (D. Utah 2002) (recognizing that the analysis for breach of warranty claims is the same as that for strict liability claims).

The Restatement of Torts gives even more credence to the idea that human tissue is not a "product" and thus not subject to products liability claims. The Restatement (Third) of Torts elaborates on products liability law in the context of human tissue and states, "Human blood and human tissue, even when provided commercially, are not subject to the rules of this Restatement." Restatement (Third) of Torts § 19(c) (Am. Law Inst. 1998). This update clarifies that human tissue, such as the Fascia Lata in this case, is not a "product" and is consistent with the nationwide policy against applying strict liability to the distribution of human tissue. *See id.* at § 19(a)–(c), cmt. c.

Although the statutory language varies modestly between jurisdictions, the public policy behind blood and human tissue shield statutes remains the same. On this matter, the California Court of Appeal stated,

> [L]egislatures have determined that the production and use of human blood and its derivatives for therapeutic purposes should be encouraged; and for this purpose those who provide these products, and who are themselves free from fault, should not be required to bear the economic loss which might otherwise be imposed under the rules of strict

> liability which are applicable to sellers of commercial products generally.

Cryolife, Inc. v. Super. Ct.., 2 Cal. Rptr. 3d 396, 405 (Cal. Ct. App. 2003) (emphasis omitted) (quoting *Hyland Therapeutics, Inc. v. Super. Ct.*, 220 Cal. Rptr. 590, 594 (Cal. Ct. App. 1985)). Moreover, there is "a nationwide antipathy over applying products-liability or strict-liability concepts to body parts such as blood and tissue." *Palermo v. Lifelink Found., Inc.*, 152 So. 3d 1177, 1181 (Miss. Ct. App. 2014). Indeed, "no court has ever applied strict liability to the distribution of human tissue." *Condos*, 208 F. Supp. 2d at 1229; *see Palermo*, 152 So. 3d at 1181.

According to the Master Complaint, Coloplast "designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products," one of which was an allograft, the Fascia Lata. First Am. Master Compl. ¶¶ 22–23. Coloplast admits in its Master Answer that it "generally packaged, labeled, marketed, sold[,] and distributed" such pelvic mesh devices. Master Answer ¶ 22. Thus, it is not in dispute that Coloplast distributed the Fascia Lata allograft. Per its labeling, the allograft is "[d]ehydrated . . . Tutoplast processed Fascia [L]ata [that] consists of human collagen." Package Insert 1. Thus, Coloplast's conduct in distributing the Fascia Lata is plainly covered by the statute and must be considered a "service."[3] Public policy, precedent, and the plain language of the statute all dictate

[3] The court acknowledges that Coloplast's status as a commercial distributor does not change the applicability of the statute. Human tissue and blood shield statutes have been interpreted to apply to for-profit entities. *See, e.g.*, *Coffee v. Cutter Biological*, 809 F.2d 191, 193 (2d Cir. 1987) (interpreting Connecticut's human tissue and blood shield statute's use of "blood bank" to include commercial manufacturers and distributors).

that the plaintiff's strict liability and breach of warranty claims must fail as a matter of law.

Accordingly, Coloplast's Motion for Summary Judgment is **GRANTED in part**, and Counts II–VII of the plaintiff's Short Form Complaint are **DISMISSED with prejudice**.

b. Negligence Claims (Counts I, XI, XII, and XIV)

Next, Coloplast argues that it is entitled to summary judgment on the plaintiff's negligence claims because she is unable to establish that any conduct by Coloplast actually caused her alleged injuries. In Oregon, the traditional elements of a common-law negligence claim "require[] a plaintiff to plead and prove that the 'defendant owed [the] plaintiff a duty, that [the] defendant breached that duty, and that the breach was the cause-in-fact of some legally cognizable damage to [the] plaintiff.'" *Towe v. Sacagawea, Inc.*, 347 P.3d 766, 774–75 (Or. 2015) (some alterations in original) (quoting *Brennen v. City of Eugene*, 591 P.2d 719, 722 (1979)). "Causation is an assessment of whether a particular act or omission in fact resulted in the particular harm that a plaintiff suffered—it turns on 'what retrospectively did happen.'" *Id.* at 775 (emphasis omitted) (quoting *Fazzolari v. Portland Sch. Dist. No. 1J*, 734 P.2d 1326, 1333 (Or. 1987) (en banc)).

According to the plaintiff's complaint and Plaintiff Fact Sheet ("PFS"), Ms. Smith was implanted with the Fascia Lata on September 8, 2010 at the Rogue Valley Medical Center in Medford, Oregon. Short Form Compl. ¶¶ 8, 10, 11; PFS 6 [ECF No. 20-2]. This is further confirmed by Dr. Beverly Fuller's operative note, which

indicates that "[a] fascia lata graft was placed posteriorly." Mot. for Summ. J. Ex. 3, at 2 [ECF No. 20-3] ("Fuller Note"). Neither Ms. Smith's complaint nor her PFS indicate that she ever received any other transvaginal mesh product, other than the Fascia Lata.

Ms. Smith claims that she first began experiencing pain and other complications from the Fascia Lata "in early 2013 approximately." PFS 8. Furthermore, she claims that she had the Fascia Lata removed on March 19, 2013 because "[i]t was causing pain and discomfort and because the mesh failed outright among other reasons." *Id.* at 7. However, the doctor who performed the removal surgery described it as a "[r]emoval of vaginal mesh/foreign body/scar tissue," Hutchings Report 2, and a pathology report from the surgery confirmed that the material removed from Ms. Smith was "[v]aginal **synthetic** mesh." Pathology Report 2 (emphasis added). From these reports, Coloplast concludes that a *synthetic* mesh product caused her alleged injuries—not the Fascia Lata, which is comprised of human tissue. Therefore, Coloplast asserts that Ms. Smith is unable to establish a causal link between her alleged injuries and the Fascia Lata distributed by Coloplast.

I disagree. Construing all reasonable inferences in favor of the nonmoving party (here, Ms. Smith), I find that there is a genuine dispute of material fact regarding whether the Fascia Lata caused Ms. Smith's alleged injuries. A single reference to synthetic mesh in the pathology report, rather than human tissue, is insufficient to establish that the Fascia Lata did not in fact cause Ms. Smith's alleged injuries.

Accordingly, Coloplast's Motion for Summary Judgment is **DENIED in part**, with respect to Counts I, XI, XII, and XIV of the plaintiff's Short Form Complaint.

c. Remaining Claims (Counts VIII–X, XIII, XV, and XVII)

Because Coloplast has not made any specific arguments addressing the plaintiff's remaining claims, and for reasons appearing to the court, Coloplast's Motion for Summary Judgment on the remaining claims (Counts VII–X, XIII, XV, and XVII) is **DENIED**.

IV. Conclusion

For the reasons stated above, it is **ORDERED** that Coloplast's Motion for Summary Judgment [ECF No. 20] is **GRANTED in part** and **DENIED in part**. The Motion is **GRANTED** with respect to Counts II–VII and is otherwise **DENIED**. Counts II–VII of the plaintiff's Short Form Complaint are **DISMISSED with prejudice**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: December 15, 2017

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE